



TECHNICAL BULLETIN

One-Tie™ Compression Coil: Information on appropriate use

Use only with Cook Medical lead-control devices:

The One-Tie Compression Coil is designed, tested, and labeled only for use with Cook Medical lead-control devices, e.g., the Liberator® Beacon® Tip Locking Stylet. **Use of the One-Tie Compression Coil with any other lead-locking device is considered an off-label use that Cook Medical cannot support and strongly discourages.**

+ Compatible devices:

For the One-Tie to be compatible with a lead-control device, such as a Liberator Beacon Tip Locking Stylet, the One-Tie must be able to securely bind a cardiac lead's proximal components to the locking stylet without adversely impacting the lead-control device's locking mechanism.

When the One-Tie Compression Coil is used with a Liberator Locking Stylet, the binding forces of the One-Tie compress the cardiac lead's proximal components together and onto the shaft of the Liberator. This squeezing action slightly reshapes the Liberator's proprietary shaft design so that the binding effect is localized and dual-location (proximal and distal) control of the cardiac lead is established.

✗ Noncompatible devices:

With lead-locking devices that have an expandable ribbon design, the ribbon contacts the cardiac lead's inner coil at various indeterminate locations within the lead's conductor coil as the ribbon expands. When a One-Tie Compression Coil is used with one of these devices, the One-Tie might bind the expandable ribbon and focus the tractional forces at an undesirable proximal location on the cardiac lead. If this happens, then the physician's control of the lead body distal to this proximal location may be significantly reduced, and control of the extraction sheath itself could be affected.



Device information:

The One-Tie Compression Coil is used during percutaneous cardiac Lead Extraction™ procedures.

This unique device has been designed to securely bind the various components within a cardiac lead's proximal end to a Cook Medical locking stylet that has been locked at the distal end of the targeted lead.

When these integral components, which may include conductor coils, cables, and insulation, are secured together and to a Cook Medical locking stylet, a transvenous guide rail is created. Extraction sheaths can be precisely controlled over the rail, which also supports the integrity of the lead body.